Outcomes of the PAHO/WHO Meeting reviewing vaccine regulatory activities for pandemic influenza H1N1.

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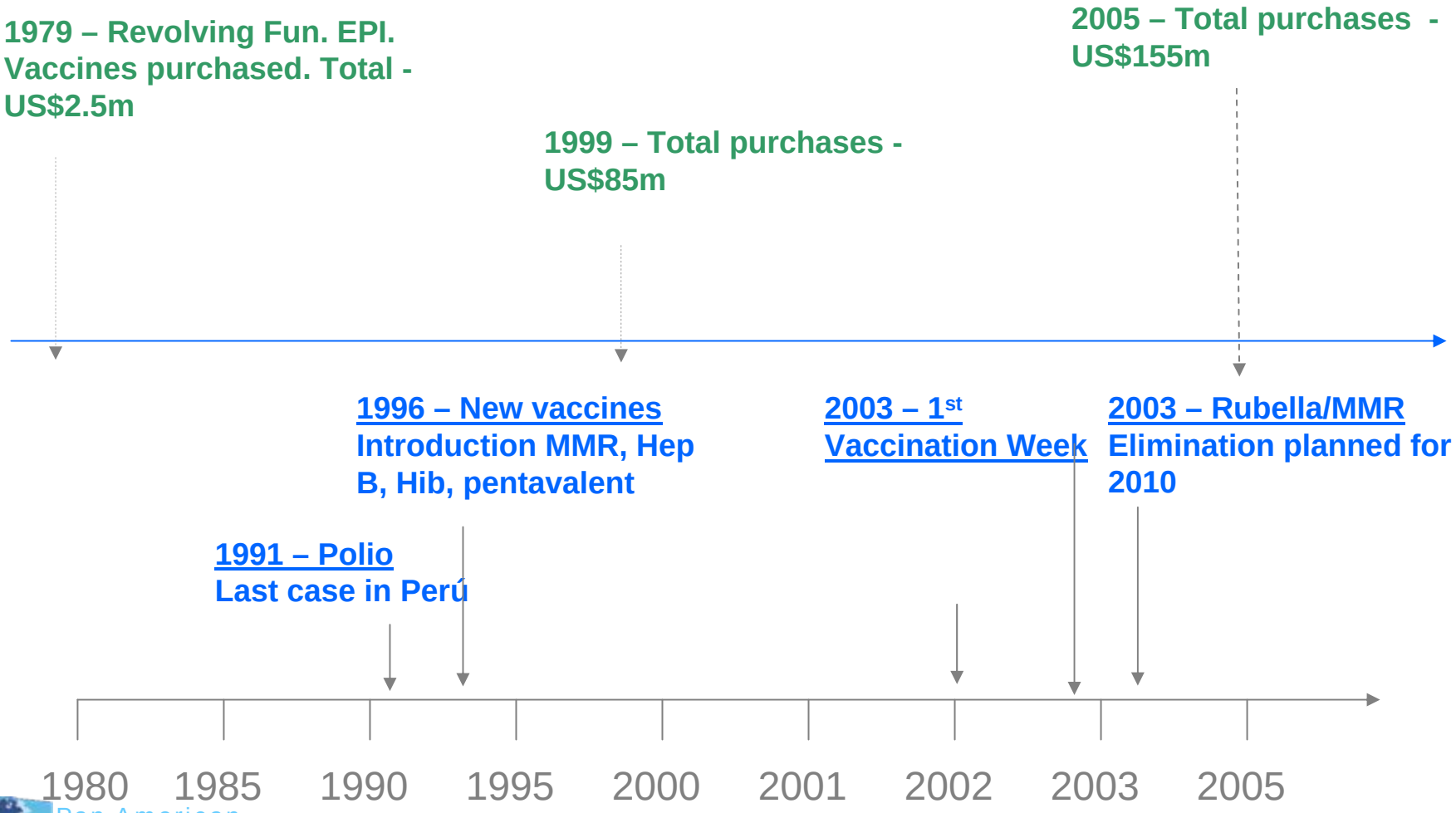
PAHO has developed several activities in support of member states in preparation for vaccination against Pandemic Influenza such as:

- **Bid solicitation for the pandemic vaccine procurement through the Revolving Fund, September 2009.**
- **Workshops in preparation for the vaccine introduction,**
- **Support to regulatory activities, etc.**

History of the PAHO Vaccine Revolving Fund



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Access to pandemic vaccine LAC Countries

Purchase ⇨

PAHO's RF — Majority countries

Direct — Some countries

Donation ⇨

WHO

Bolivia	Cuba
El Salvador	Guatemala
Guyana	Haiti
Honduras	Nicaragua
Paraguay	Suriname

Deployment: November; December

Meeting organized in response to the countries' request for advice on regulation for the new H1N1 pandemic influenza vaccines

Held in Buenos Aires, Argentina. December 2-4, 2009

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Meeting objectives

To discuss regulatory issues related with the pandemic influenza vaccine H1N1 focusing on:

1.- Licensing pathways

2.- Lot release

3.- Post-marketing surveillance activities

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Participating countries
Representatives from NRAs and EPIs (Latin American and Caribbean countries)

- Argentina, Brazil, Chile, Cuba, Ecuador, Mexico, Panama, Paraguay, Peru and Uruguay

Vaccines submitted for licensing to participating National Regulatory Authorities

Inactivated:

- Adjuvanted and unadjuvanted

  several adjuvant compositions, all of them based on organic oil (squalene)
- Produced in eggs or cell culture
- Several presentations (single or multidose, vial or syringe)
- From more than seven manufactures (GSK, Sanofi-Pasteur, Novatis, Green Cross, Panacea, Sinovac, Omnivest, etc)

Conclusions:

Licensing:

– Need to facilitate acces to pandemic influenza vaccine of quality in a timely way by establishing fast track licensing procedures

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License criteria

Indicated in the WHO document *Regulatory Preparedness for Human Pandemic Influenza Vaccines WHO/BS/07.2007;*

- Based on the public license from National Regulatory Authorities: FDA, EMEA, Health Canada, TGA and Japan Regulatory Agency **or,**

- Based on the WHO prequalification (currently five products from three different manufacturers are prequalified)

Requesting the manufacturer:

- To keep the NRA informed on the progress in the evaluation of the product regarding efficacy, safety and stability.

- To present a post-marketing surveillance plan to be approved and supervised by the NRA.

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Conclusions (Cont…)

Lot release:

- To perform lot release based on protocol review
- To avoid testing duplication, taking into consideration the current difficulties in the methodologies for antigen quantification.

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Conclusions (cont…)

Regional post marketing surveillance activities:

- Countries committed to establish the base line values of GBS in adults
- Countries will look for mechanisms to encourage the notification of adverse reactions (GBS, anaphylactic shock, deaths, spontaneous abortions, etc.)
- PAHO workshop with NRAs and EPIs to coordinate post-marketing surveillance activities (in coordination with WHO (Patrick Zuber) and FDA (Hector Izurieta), to be held on January, 26-27, 2010

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General conclusions

From this meeting and meetings sustained with UNASUR and Ministers of Health from Latin America and Caribbean countries:

- **Need to generate regional capacity for production and regulation of influenza vaccines in order to be able to respond to pandemics**

- **Some regional initiatives for vaccine production capacity initiated. Need to couple with plans to strengthen where needed independent regulatory oversight and know how in influenza vaccine**

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